K063408

510(k) Summary
for
CTLOGICS Navigation System

FEB 2 8 2007

1. Submitter Name and Address:

Praxim
"Le Grand Sablon"
4, Avenue de l'Obiou
38 700 La Tronche
France

Contact Name: Jihane ZEMMOURI
Telephone: (0033) 4 76 54 95 03

Date Prepared: February 8th, 2007

2. Device Name:

Proprietary Name: CTLOGICS Navigation System
Common/Usual Name: Image guided surgical navigation system
Classification Name: Computed tomography x-ray system (accessory)

3. Equivalent to:

K053159 – VectorVision spine – BrainLAB AG
K062146 – UNI KNEE SURGETICS Navigation System – PRAXIM S.A.
K022239 – Surgetics ENTact Endonasal Navigation System – PRAXIM S.A.

4. Intended Use:

The CTLOGICS Navigation System is an optically based surgical navigation system. It is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures.

The system which uses patient's preoperative image data is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone, or a vertebra can be identified relative to CT-based model of the anatomical structure.

Example procedures include but are not limited to:

Posterior spinal implant procedures such as pedicle screw placement, kyphoplasty and vertebroplasty procedures, thoracic spine surgery, tumor surgery on the spinal column.

Superolateral and deltopectoral shoulder procedures, such as guiding the glenoid component on the scapula.

5. Device Description:

The CTLOGICS Navigation System consists of the following major components and subsystems:

- The Surgetics Station or the NanoStation, consisting of a mobile computer system and an optical localizer
- Ancillary instruments and reflective markers used for reference and registration
- CTLOGICS Software

6. Technological Characteristics and Substantial Equivalence

The CTLOGICS Navigation System is specifically designed for use in surgeries using pre-acquired patient images. During these surgeries, the system allows the navigation of instruments on pre-acquired images. It can be used in posterior spinal implant procedures, superolateral shoulder procedures, and deltopectoral shoulder procedures.

7. Performance Testing

The CTLOGICS Navigation System was tested to assess that no safety and efficiency issues were raised in the device. Analyses show that the accuracy and performance of the system was adequate for its intended use and not reduced in comparison to the predicate devices. In conclusion the CTLOGICS Navigation System is substantially equivalent to the VectorVision Spine #K053159, the Surgetics ENTact Endonasal Navigation System #K022239 and Uni Knee Navigation System #K062146.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Praxim Medivision, SA
% Jihane Zemmouri
Quality Manager
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4 Avenue De L'Obiou
La Tronche, France 38700

FEB 2 8 2007

Re: K063408
Trade/Device Name: CTLOGICS Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: February 8, 2007
Received: February 14, 2007

Dear Jihane Zemmour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

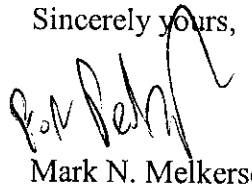
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063408

STATEMENT OF INDICATIONS FOR USE

CTLOGICS Navigation System

510(k) Number (if known): K063408

Device Name: CTLOGICS Navigation System

Indications for Use:

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Superolateral and deltopectoral shoulder procedures, such as guiding the glenoid component on the scapula.

Prescription Use ___X__ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K063408